MERCK / Schering-Plough Pharmaceuticals

PO Box 1000
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March 30, 2008

Dear Health Care Professional:

Today, March 30, 2008, additional results from the ENHANCE* study were presented at the American College of Cardiology Scientific Sessions and published online in *The New England Journal of Medicine*.

Merck/Schering-Plough Pharmaceuticals (MSP) is pleased that the full published results of the ENHANCE trial have now been presented and that a scientific discussion of the results is under way. As we have stated before, MSP, Merck, and Schering-Plough stand behind the low-density lipoprotein cholesterol (LDL-C) efficacy and safety profiles of both VYTORIN® (ezetimibe/simvastatin) and ZETIA® (ezetimibe). The results of this study do not change that position. In fact, we believe this study adds to the body of knowledge about cholesterol treatment in a patient population with heterozygous familial hypercholesterolemia (HeFH).

We encourage you to read the published study results, which are available on *The New England Journal of Medicine* Web site (www.nejm.org). If you prefer, you can call 1-800-285-6345 to request a copy of the paper. Please see the accompanying press release from MSP regarding the ENHANCE study. Finally, additional information is available at www.msppharma.com.

In light of the extensive news coverage recently, MSP, Merck, and Schering-Plough would like to make several points regarding VYTORIN and ZETIA.

Lowering LDL-C remains the primary target of lipid-modifying therapy.
National guidelines, based on more than 20 years of scientific evidence, recommend LDL-C lowering as the primary target of lipid therapy. These important findings are reflected in the National Cholesterol Education Panel (NCEP) guidelines. The NCEP ATP III 2004 Update recommended an LDL-C target of less than 100 mg/dL in high-risk patients and an optional LDL-C goal of less than 70 mg/dL in very high-risk patients.[1] Many patients with high LDL-C are not at recommended treatment goals.[2]

VYTORIN and ZETIA are available therapeutic options for the treatment of high cholesterol.
MSP recognizes the important role of statins in the treatment of high cholesterol. In fact, VYTORIN contains simvastatin. Both VYTORIN, and ZETIA in combination with statins, have been extensively studied prior to and since approval. VYTORIN is indicated as adjunctive therapy to diet to reduce LDL-C in patients with hypercholesterolemia when diet alone is not enough. Use of VYTORIN as initial therapy has been extensively studied in patients with hypercholesterolemia. Data also support the use of ZETIA in patients with hypercholesterolemia currently on a statin not at goal in addition to a healthy diet when diet alone is not enough. The LDL-C–lowering efficacy and safety profiles of these products have been demonstrated in multiple studies and are reflected in the approved product labels.

VYTORIN contains 2 active ingredients: ezetimibe and simvastatin. No incremental benefit of VYTORIN on cardiovascular morbidity and mortality over and above that demonstrated for

* Ezetimibe and Simvastatin in Hypercholesterolemia Enhances Atherosclerosis Regression (ENHANCE).

simvastatin has been established. The effects of ZETIA® (ezetimibe), either alone or in addition to a statin, on the risk of cardiovascular morbidity and mortality have not been established.

Patients who are taking VYTORIN® (ezetimibe/simvastatin) or ZETIA may continue to have questions. What should you consider telling them as a health care professional?
When counseling your patients on VYTORIN or ZETIA, we would encourage you to respond based on your independent clinical judgment and your knowledge of your patients and goals you set for them.

Important Information About ZETIA:

ZETIA, administered alone or in combination with an HMG-CoA reductase inhibitor (statin), is indicated as adjunctive therapy to diet for the reduction of elevated TOTAL-C, LDL-C, and Apo B in patients with primary (heterozygous familial and nonfamilial) hypercholesterolemia when diet alone is not enough.

ZETIA is not indicated to slow the progression of atherosclerosis.

Contraindications for ZETIA: hypersensitivity to any component of this medication.
Contraindications when used with a statin: active liver disease; unexplained persistent elevations of serum transaminases. Statins are contraindicated in pregnant and nursing women; refer to the statin label for details.

When ZETIA was coadministered with a statin, consecutive elevations in serum transaminases (≥3 × ULN) were slightly higher (1.3%) than those of statins alone (0.4%). Liver function tests should be performed when ZETIA is added to statin therapy and according to statin recommendations.

Patients should be advised to promptly report muscle pain, tenderness, or weakness. Discontinue drug if myopathy is diagnosed or suspected.

ZETIA is not recommended in patients with moderate or severe hepatic insufficiency.

Exercise caution when using ZETIA and cyclosporine concomitantly because exposure to both drugs is increased. Cyclosporine concentrations should be monitored in these patients.

In clinical trials, the most frequent side effects for ZETIA alone vs placebo included back pain (4.1% vs 3.9%), arthralgia (3.8% vs 3.4%), and fatigue (2.2% vs 1.8%); for ZETIA + statin vs statin or placebo alone: back pain (4.3% vs 3.7% vs 3.5%), abdominal pain (3.5% vs 3.1% vs 2.3%), and fatigue (2.8% vs 1.4% vs 1.9%).

Before prescribing ZETIA, please read the accompanying Prescribing Information.
For additional copies of the Prescribing Information, call 1-866-637-2501, visit zetia.com, or contact your MSP representative.

Important Information About VYTORIN:

VYTORIN is indicated as adjunctive therapy to diet for the reduction of elevated TOTAL-C, LDL-C, Apo B, TG, and non–HDL-C, and to increase HDL-C in patients with primary (heterozygous familial and nonfamilial) hypercholesterolemia or mixed hyperlipidemia when diet alone is not enough.

VYTORIN® (ezetimibe/simvastatin) is not indicated to slow the progression of atherosclerosis.

Contraindications for VYTORIN: hypersensitivity to any component of this medication; active liver disease; unexplained persistent elevations of serum transaminases; and women who are pregnant, nursing, or may become pregnant.

SELECTED CAUTIONARY INFORMATION
Skeletal Muscle: Myopathy sometimes takes the form of rhabdomyolysis with or without acute renal failure secondary to myoglobinuria, and rare fatalities have occurred. The risk of myopathy/rhabdomyolysis is dose related. Tell patients to promptly report muscle pain, tenderness, or weakness. Discontinue drug if myopathy is suspected or CPK levels rise markedly.

Myopathy Caused by Drug Interactions: Use of VYTORIN with itraconazole, ketoconazole, erythromycin, clarithromycin, telithromycin, HIV protease inhibitors, nefazodone, or large quantities of grapefruit juice (>1 quart daily) should be avoided because of the increased risk of myopathy, particularly at higher doses.

The concomitant use of VYTORIN and fibrates (especially gemfibrozil) should be avoided. Although not recommended, the dose of VYTORIN should not exceed 10/10 mg if used with gemfibrozil.

The benefit of further alterations in lipid levels by the combined use of VYTORIN with niacin should be carefully weighed against the potential risks of myopathy. The dose of VYTORIN should not exceed 10/10 mg daily in patients receiving cyclosporine or danazol, and 10/20 mg daily in patients receiving amiodarone or verapamil, due to the increased risk of myopathy. The combined use of VYTORIN at doses higher than 10/20 mg daily with amiodarone or verapamil should be avoided unless the clinical benefit is likely to outweigh the increased risk of myopathy.

Liver: It is recommended that liver function tests be performed before the initiation of treatment and thereafter when clinically indicated. Additional tests are recommended prior to and 3 months after titration to the 10/80-mg dose, and semiannually for the first year thereafter.

The incidence of consecutive elevations (≥3 × ULN) in serum transaminases was 1.7% overall and appeared to be dose related, with an incidence of 2.6% for 10/80 mg. In long-term (48-week) extensions, which included both newly treated and previously treated patients, the incidence was 1.8% overall and 3.6% for 10/80 mg. These elevations were generally asymptomatic, not associated with cholestasis, and reversible whether treatment was maintained or discontinued.

VYTORIN is not recommended in patients with moderate or severe hepatic insufficiency.

In clinical trials, the most commonly reported side effects, regardless of cause, included headache (6.8%), upper respiratory tract infection (3.9%), myalgia (3.5%), influenza (2.6%), and extremity pain (2.3%).

VYTORIN® (ezetimibe/simvastatin) tablets contain ezetimibe and simvastatin: 10 mg of ezetimibe and 10, 20, 40, or 80 mg of simvastatin (VYTORIN 10/10, 10/20, 10/40, or 10/80 mg, respectively).

Before prescribing VYTORIN, please read the accompanying Prescribing Information. For additional copies of the Prescribing Information, call 1-866-637-2501, visit vytorin.com, or contact your MSP representative.

Sincerely,

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US Pharmaceuticals, Merck

Craig B. Granowitz, MD, PhD
Vice President
Global Medical Affairs
Schering-Plough

Enclosures: Merck/Schering Plough Pharmaceuticals Press Release
Prescribing Information for VYTORIN
Prescribing Information for ZETIA® (ezetimibe)

References: **1.** Grundy SM, Cleeman JI, Merz CNB, et al; for Coordinating Committee of the National Cholesterol Education Program. Implications of recent clinical trials for the National Cholesterol Education Program Adult Treatment Panel III guidelines. *Circulation.* 2004;110(2):227–239. **2.** Keevil JG, Cullen MW, Gangnon R, McBride PE, Stein JH. Implications of cardiac risk and low-density lipoprotein cholesterol distributions in the United States for the diagnosis and treatment of dyslipidemia: data from the National Health and Nutrition Examination Survey 1999 to 2002. *Circulation.* 2007;115(11):1363–1370.

MERCK / Schering-Plough Pharmaceuticals News Release

FOR IMMEDIATE RELEASE

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Merck/Schering-Plough Pharmaceuticals Comments on Results of the ENHANCE Study

Study Presented at American College of Cardiology Scientific Sessions and Published in On-Line Version of *The New England Journal of Medicine*

CHICAGO, March 30, 2008 -- Results of ENHANCE (**E**zetimibe a**N**d simvastatin in **H**ypercholesterolemia enh**AN**ces atheros**C**lerosis r**E**gression), an imaging trial in 720 patients with heterozygous familial hypercholesterolemia (HeFH), a rare genetic condition that causes very high levels of LDL "bad" cholesterol and greatly increases the risk for premature coronary artery disease, were presented at the 57th annual scientific sessions of the American College of Cardiology and also were published on-line in *The New England Journal of Medicine*[i].

As previously reported on Jan. 14, 2008, despite the fact that ezetimibe/simvastatin 10/80 mg (VYTORIN® *) significantly lowered LDL "bad" cholesterol more than simvastatin 80 mg alone, there was no significant difference between treatment with ezetimibe/simvastatin and simvastatin alone on the pre-specified primary endpoint, a change in the thickness of carotid artery walls over two years as measured by ultrasound. There also were no significant differences between treatment with ezetimibe/simvastatin and simvastatin on the four pre-specified key secondary endpoints: percent of patients manifesting regression in the average carotid artery intima-media thickness (CA IMT); proportion of patients developing new carotid artery plaques >1.3 mm; changes in the average maximum CA IMT; and changes in the average CA IMT plus in the average common femoral artery IMT.

In ENHANCE, when compared to simvastatin alone, ezetimibe/simvastatin significantly lowered LDL "bad" cholesterol, as well as triglycerides and C-reactive protein (CRP).

- more -

*** VYTORIN includes the two components (ezetimibe and simvastatin) in one tablet.**

Ezetimibe/simvastatin is not indicated for the reduction of CRP. In the ENHANCE study, as previously reported, the overall safety profile of ezetimibe/simvastatin in the study was generally consistent with the product label.

"LDL cholesterol remains the primary target of lipid-modifying therapy and physicians should continue to lower patients' elevated LDL cholesterol and get their patients to their goals based on guidelines," said Michael Davidson, M.D., professor, director of preventive cardiology, The University of Chicago, Pritzker School of Medicine.

In the ENHANCE publication, the authors provided three theoretical explanations why, despite ezetimibe/simvastatin significantly lowering LDL "bad" cholesterol more than simvastatin (56 percent vs. 39 percent, $p<0.01$), there was no significant difference between treatment groups on the primary endpoint and four key secondary endpoints: (1) lowering of LDL cholesterol with non-statin therapy, such as ezetimibe, might affect IMT differently than statin therapy, (2) the imaging technology selected was not sensitive enough to detect a difference, or (3) that these HeFH patients were extensively pretreated with lipid-lowering therapy, thereby limiting the amount that CA IMT could change with further LDL cholesterol-lowering therapy, consequently limiting the ability to detect a differential response to the two treatments. The authors concluded that the reason for the failure to observe an incremental effect on CA IMT thickness in spite of a reduction of level of LDL cholesterol remains unknown.

In the publication, the authors addressed the premise that the lack of a difference in change of mean CA IMT between ezetimibe/simvastatin and simvastatin despite greater LDL cholesterol-lowering could be attributed to lipid-independent effects of statins on arteries. The authors presented several facts that argued against this concept, including a discussion of clinical studies involving statin and non-statin therapeutic approaches that demonstrated that cardiovascular risk reductions were associated with the degree of LDL-cholesterol lowering. The authors suggested that clinical outcomes data are needed to answer this question.

As for the hypothesis that the results may reflect the imaging technology, the authors noted this seems unlikely given the precision of the imaging measurement results seen in the ENHANCE trial.

With respect to the hypothesis that the ENHANCE results were due to the characteristics of the patients studied, the authors pointed out that in an earlier imaging study (extension of ASAP or **A**torvastatin vs. **S**imvastatin on **A**therosclerosis **P**rogression study) use of potent lipid-lowering therapy in HeFH patients produced "regression" or "thinning" of CA IMT during the first one to two years of therapy, but further decreases during the following two years on the same therapy were not seen. In ENHANCE, approximately 80 percent of the enrolled patients

reported taking statin treatment at the time of screening for the study, and had a mean baseline CA IMT of 0.69 to 0.70 mm. In another recent IMT study in HeFH patients (RADIANCE 1 or **R**ating **A**therosclerotic **D**isease **C**hange by **I**maging with **A** **N**ew **CE**TP Inhibitor study), the baseline CA IMT was also lower than in the earlier IMT study and similar to ENHANCE and, importantly, the pattern of change in CA IMT in this IMT study was very similar to that observed in both treatment groups in the ENHANCE study.

The authors noted that “these data raise the possibility that there may be limits to the extent to which the lowering of LDL cholesterol levels can result in a further decrease in the progression of intima-media thickness in the context of previous statin therapy and a modest baseline intima-media thickness[ii]."

"Although a definitive explanation is never possible with a finding like this, we believe that the most likely explanation for the failure to see a significant difference between treatment groups in ENHANCE relates to the behavior of IMT in this population of HeFH patients," noted Thomas Musliner, M.D., executive director, Cardiovascular Disease, Clinical Research, Merck Research Laboratories. "The large majority of these patients were previously treated with LDL cholesterol-lowering therapy and presumably experienced an effect on CA IMT from that treatment, as reflected in the patients' relatively low CA IMT values when they began the study. The findings of the ASAP extension, RADIANCE 1 and ENHANCE suggest there are limits to how much IMT can be decreased in HeFH study cohorts in the context of the widespread and prolonged use of effective LDL cholesterol-lowering treatment starting at an earlier age, which is now the standard of care for these patients."

Endpoint data and cardiovascular events

ENHANCE investigators found no statistically significant difference between the two treatment groups on the primary endpoint, the change in the average CA IMT at three carotid artery locations. The change from baseline in the mean (average) CA IMT in the ezetimibe/simvastatin group was 0.0111 mm, which did not significantly differ from the simvastatin group’s change of 0.0058 mm (P=0.29). The median data for the primary endpoint, which also showed no statistical difference between treatments, was 0.0058 mm in the ezetimibe/simvastatin group and 0.0095 mm for the simvastatin group. The treatment groups also did not have statistically significant differences for each of the three carotid artery locations that comprised the primary endpoint: the common carotid, the internal carotid and the carotid bulb. The data for these analyses, key secondary endpoints and cardiovascular events are included in the attachment.

The ENHANCE study was not designed nor powered to evaluate cardiovascular clinical events. IMPROVE-IT is underway and is designed to provide cardiovascular outcomes data for ezetimibe/simvastatin in patients with acute coronary syndrome. No incremental benefit of ezetimibe/simvastatin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established.

Lipid parameters of LDL cholesterol, triglycerides and HDL cholesterol; and C-reactive protein

Over the two-year period of the ENHANCE study based upon the "last observation carried forward" endpoint approach, the group treated with ezetimibe/simvastatin had a 56 percent mean reduction of LDL cholesterol (from a baseline of 319 mg/dL) that was significantly greater than the 39 percent mean reduction of LDL cholesterol (from a baseline of 318 mg/dL) in the group treated with simvastatin alone ($P<0.01$). The LDL cholesterol-lowering observed in patients treated with ezetimibe/simvastatin in the ENHANCE trial was generally consistent with the LDL cholesterol-lowering of ezetimibe/simvastatin seen in separate head-to-head studies vs. simvastatin, vs. Crestor® and vs. Lipitor®.

In addition, by study completion, the ezetimibe/simvastatin group had a 30 percent median reduction in triglycerides (from baseline 157 mg/dL), significantly more than the 23 percent median reduction (from baseline 160 mg/dL) in the simvastatin group ($P<0.01$). Also, the ezetimibe/simvastatin group had a 49 percent median reduction in CRP (from baseline 1.70 mg/L), significantly more than the 24 percent median reduction in CRP (from baseline 1.70 mg/L) in the simvastatin group ($P<0.01$). The ezetimibe/simvastatin group had a 10 percent increase (from baseline 46.7 mg/dL) in HDL "good" cholesterol; the simvastatin group had an 8 percent increase from baseline 47.4 mg/dL ($P=0.05$, no statistical significance).

Safety data

As previously reported, the overall safety profiles of ezetimibe/simvastatin and simvastatin alone were similar and generally consistent with their product labels. Both medicines were generally well tolerated. Also, the overall incidence rates of treatment-related adverse events were 34 percent for ezetimibe/simvastatin (122/357) and 29 percent (107/363) for simvastatin only; the incidence rates for discontinuations due to adverse events were 8.1 percent for ezetimibe/simvastatin (29/357) and 9.4 percent for simvastatin only (34/363). Additional adverse event data are included in the attachment.

About the study design and methodology

The ENHANCE study was an international two-year, randomized, double-blind, controlled trial in 720 HeFH patients between the ages of 30 to 75. All of the ENHANCE patients had HeFH, which affects approximately 0.2 percent of the population. The rationale for studying HeFH patients is that these patients are known to be at increased risk for premature coronary artery disease and, if untreated, exhibit increased IMT progression rates beginning in childhood. Prior LDL cholesterol-lowering therapy of any kind was not an exclusion criterion for ENHANCE, although such therapies were discontinued at the start of the study. Also, there wasn't a minimum value for CA IMT specified for inclusion in study. Following a six-week, single blind, placebo lead-in/drug “wash-out” period, patients were randomized to receive either daily ezetimibe/simvastatin 10/80 mg (N=357) or daily simvastatin 80 mg (N=363).

ENHANCE investigators took digitized single-frame CA IMT images at the three locations of the patients’ right and left carotid arteries, the main arteries in the neck that provide blood to the brain. These images were taken at several time points: study baseline, 6, 12, 18 and 24 months.

“Examination of the CA IMT collected during ENHANCE proved to be a far more challenging process than originally anticipated when the study design was drawn up. Therefore, preparation of the images for entry into a database took significantly longer than expected, as the blinded investigators and CA IMT evaluators took numerous steps in 2006 and 2007 to address image quality control and finalize the analysis,” said Enrico P. Veltri, M.D., co-author of the ENHANCE study publication and group vice president, Global Clinical Research, Cardiovascular and Metabolic Diseases, Schering-Plough Research Institute. “Our companies acted with integrity and good faith in connection with the trial,” he said.

Important information about VYTORIN

Ezetimibe/simvastatin is indicated as adjunctive therapy to diet for the reduction of elevated total cholesterol, LDL cholesterol, Apo B, triglycerides and non-HDL cholesterol and to increase HDL cholesterol in patients with primary (heterozygous familial and non-familial) hypercholesterolemia or mixed hyperlipidemia.

Ezetimibe/simvastatin is also indicated for the reduction of elevated total cholesterol and LDL cholesterol in patients with homozygous familial hypercholesterolemia, as an adjunct to other lipid-lowering treatments (e.g. LDL apheresis) or if such treatments are unavailable.

Ezetimibe/simvastatin is a prescription medicine and should not be taken by people who are hypersensitive to any of its components. Ezetimibe/simvastatin should not be taken by anyone with active liver disease or unexplained persistent elevations of serum transaminases.

Women who are of childbearing age (unless highly unlikely to conceive), are nursing or who are pregnant should not take ezetimibe/simvastatin.

Selected cautionary information for VYTORIN

Muscle pain, tenderness or weakness in people taking ezetimibe/simvastatin should be reported to a doctor promptly because these could be signs of a serious side effect. Ezetimibe/simvastatin should be discontinued if myopathy is diagnosed or suspected. To help avoid serious side effects, patients should talk to their doctor about medicine or food they should avoid while taking ezetimibe/simvastatin.

In three placebo-controlled, 12-week trials, the incidence of consecutive elevations (≥3 X ULN) in serum transaminases were 1.7 percent overall for patients treated with ezetimibe/simvastatin and 2.6 percent for patients treated with ezetimibe/simvastatin 10/80 mg. In controlled long-term (48-week) extensions, which included both newly-treated and previously-treated patients, the incidence of consecutive elevations (≥3 X ULN) in serum transaminases was 1.8 percent overall and 3.6 percent for patients treated with ezetimibe/simvastatin 10/80 mg. These elevations in transaminases were generally asymptomatic, not associated with cholestasis and returned to baseline after discontinuation of therapy or with continued treatment. Doctors should perform blood tests before, and periodically during treatment with ezetimibe/simvastatin when clinically indicated to check for liver problems. People taking ezetimibe/simvastatin 10/80 mg should receive an additional liver function test prior to and three months after titration and periodically during the first year.

Due to the unknown effects of increased exposure to ezetimibe in patients with moderate or severe hepatic insufficiency, ezetimibe/simvastatin is not recommended in these patients. The safety and effectiveness of ezetimibe/simvastatin with fibrates have not been established; therefore, co-administration with fibrates is not recommended. Caution should be exercised when initiating ezetimibe/simvastatin in patients treated with cyclosporine and in patients with severe renal insufficiency.

Ezetimibe/simvastatin has been evaluated for safety in more than 3,800 patients in clinical trials and was generally well tolerated at all doses (10/10 mg, 10/20 mg, 10/40 mg, 10/80 mg). In clinical trials, the most commonly reported side effects, regardless of cause, included headache (6.8 percent), upper respiratory tract infection (3.9 percent), myalgia (3.5 percent), influenza (2.6 percent) and extremity pain (2.3 percent).

About Merck/Schering-Plough Pharmaceuticals

Merck/Schering-Plough Pharmaceuticals is a joint venture between Merck & Co., Inc. and Schering-Plough Corporation formed to develop and market in the United States new

prescription medicines in cholesterol management. The collaboration includes worldwide markets (excluding Japan). VYTORIN is also marketed as INEGY outside the U.S.

Merck Forward-looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the risk factors and cautionary statements in Item 1A of Merck's Form 10-K for the year ended Dec. 31, 2007, and in any risk factors or cautionary statements contained in the Company's periodic reports on Form 10-Q or current reports on Form 8-K, which the Company incorporates by reference.

Schering-Plough Disclosure Notice

The information in this press release includes certain “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to marketing for VYTORIN and ZETIA® (ezetimibe). Forward-looking statements relate to expectations or forecasts of future events. Schering-Plough does not assume the obligation to update any forward-looking statement. Many factors could cause actual results to differ materially from Schering-Plough’s forward-looking statements, including market forces, economic factors, product availability, patent and other intellectual property protection, current and future branded, generic or over-the-counter competition, the regulatory process, and any developments following regulatory approval, among other uncertainties. For further details about these and other factors that may impact the forward-looking statements, see Schering-Plough’s Securities and Exchange Commission filings, including Part I, Item IA. “Risk Factors” in Schering-Plough’s 2007 10-K/A.

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Prescribing information and patient product information for VYTORIN is attached.

[i] N Engl J Med 2008; 358:1431-43.
[ii] N Engl J Med 2008; 358:1431-43.

MERCK / Schering-Plough Pharmaceuticals

Results From ENHANCE Study Presented at American College of Cardiology Scientific Sessions and Published in On-Line Version of *The New England Journal of Medicine*

Data (change from study baseline)	Drug				*P* Value (Mean only) NS= not statistically significant
	Simvastatin (80 mg)		VYTORIN (10/80 mg ezetimibe/ simvastatin)		
	Mean	Median	Mean	Median	
Baseline IMT					
Baseline CA IMT (mm)	0.70	0.69	0.69	0.68	
Primary Endpoint					
Change in CA IMT at three CA sites (mm)	0.0058	0.0095	0.0111	0.0058	=0.29 (NS)
Individual Components of Primary Endpoint					
Far common carotid IMT (mm)	0.0024	0.0043	0.0019	0.0010	=0.93 (NS)
Internal carotid IMT (mm)	-0.0007	0.0057	0.0099	0.0066	=0.21 (NS)
Carotid bulb IMT (mm)	0.0062	0.0099	0.0144	0.0107	=0.37 (NS)
Four Key Secondary Endpoints					
Patients manifesting regression in CA IMT	44.4 percent (142/320)		45.3 percent (146/322)		=0.92 (NS)
Patients developing new CA plaques, pre-specified as lesions of 1.3 mm or larger in thickness	2.8 percent (9/320)		4.7 percent (15/322)		=0.20 (NS)
Change in the maximum CA IMT, pre-specified as the far wall maximum CA IMTs for the common carotids, carotid bulb, and internal carotids (mm)	0.0103	0.0103	0.0175	0.0160	=0.27 (NS)
Change in the CA IMT plus the common femoral artery IMT (mm)	0.0033		0.0182		=0.15 (NS)
Lipid Parameters: LDL-C, Triglycerides, HDL-C; and C-reactive Protein					
LDL-C	-39.1 percent (317.8± 66.1 to 192.7±60.3 mg/dL)		-55.6 percent (319.0± 65.0 to 141.3±52.6 mg/dL)		<0.01
Triglycerides		-23.2 percent (160 to 120 mg/dL)		- 29.8 percent (157 to 108 mg/dL)	<0.01 (median)
HDL-C	+7.8 percent (47.4±13.2 to 50.7±14.7 mg/dL)		+10.2 percent (46.7±11.3 to 50.9±12.8 mg/dL)		=0.05
C-reactive Protein		-23.5 percent (1.70 to 1.20 mg/dL)		-49.2 percent (1.70 to 0.90 mg/dL)	<0.01 (median)
Pre-Specified Cardiovascular Events					
Cardiovascular deaths	1/363		2/357		
Nonfatal heart attacks	2/363		3/357		
Nonfatal strokes	1/363		1/357		
Revascularization	5/363		6/357		
Adverse Events					
Incidence of consecutive elevations of serum transaminases (≥ 3x ULN)	2.2 percent (8/360)		2.8 percent (10/356)		
Incidence of elevated creatine phosphokinase (CPK) (≥ 10x ULN)	2.2 percent (8/360)		1.1 percent (4/356)		
Cases of elevated CPK associated with muscle symptoms	0.3 percent (1 case)		0.6 percent (2 cases)		

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